

Appl. No. : 10/714,691
Filed : November 17, 2003

AMENDMENTS TO THE CLAIMS

WHAT IS CLAIMED IS:

1-35 (Cancelled)

36. (New) A method for detecting the presence of mastitis or a mastitis inducing pathogen in a milk sample of a mammal species, comprising:

providing a milk sample from a mammal species;

conducting an assay by exposing the milk sample to at least two antibodies, wherein each of the at least two antibodies is specific to a corresponding antigen from an indicator, wherein the indicator is selected from the group consisting of: one or more distinct pathogens of the mammal species and a somatic cell of the mammal species, and wherein the assay comprises determination of presence or absence of antibody reaction with the at least two indicators in the sample; and

relating presence of the antibody reaction in the assay to mastitis in the mammal species or a mastitis-inducing pathogen in the milk sample.

37. (New) The method of Claim 36, wherein the assay is completed in less than 24 hours.

38. (New) The method of Claim 36, wherein the assay is completed in less than 30 minutes.

39. (New) The method of Claim 36, wherein presence of antibody reaction for at least one indicator in the sample is indicative of mastitis.

40. (New) The method of Claim 36, wherein presence of antibody reaction for all of the indicators in the sample is indicative of mastitis.

41. (New) The method of Claim 36, wherein the milk sample exists in at least two phases before the assay, and wherein at least one phase is used in the assay.

42. (New) The method of Claim 36, wherein the milk sample is diluted before the assay.

43. (New) The method of Claim 36, wherein the milk sample is subdivided before the assay.

44. (New) The method of Claim 36, wherein the assay comprises a plurality of separate tests on the sample.

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45. (New) The method of Claim 36, wherein the cream is removed from the top of the milk before exposing.

46. (New) The method of Claim 36, wherein the milk sample is treated to remove at least about 50% of the fat and/or the casein.

47. (New) The method of Claim 46 wherein the treatment comprises adding a detergent to remove the fat globules and precipitating the casein with acid.

48. (New) The method of Claim 36, wherein the somatic cell is a granulocyte.

49. (New) The method of Claim 48, wherein the granulocyte is a neutrophil.

50. (New) The method of Claim 36, wherein the pathogen is selected from the group consisting of a bacterium, a virus, and a fungus.

51. (New) The method of Claim 50 wherein the pathogen is a bacterium selected from the group consisting of: *Streptococcus spp.*, *Enterococcus spp.*, *Staphylococcus spp.*, *Micrococcus spp.*, *Escherischia coli*, *Klebsiella spp.* Enterobacteria, *Serratia spp.*, *Pseudomonas spp.*, *Proteus spp.*, *Pasteurella spp.*, *Corynebacterium bovis*, *Arcanobacterium pyogenes*, *Mycobacterium spp.*, *Bacillus spp.*, and *Mycoplasma spp.*

52. (New) The method of Claim 50 wherein the fungus is a yeast or a mold selected from the group consisting of: *Nocardia spp.* and *Prototheca*.

53. (New) The method of Claim 50 wherein the pathogen is selected from the group consisting of: *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

54. (New) The method of Claim 50 wherein the pathogen is *Staphylococcus aureus*

55. (New) The method of Claim 50 wherein the pathogen is a coagulase-negative *Staphylococcus*.

56. (New) The method of Claim 51 wherein the mycoplasma is selected from the group consisting of *Mycoplasma bovis*, *Mycoplasma californicum*, and *Mycoplasma bovis genitaliae*.

57. (New) The method of Claim 36, wherein the assay comprises determination of presence or absence of antibody reaction with at least 3 indicators in the sample.

58. (New) The method of Claim 36, wherein the assay comprises determination of presence or absence of antibody reaction with at least 7 indicators in the sample.

59. (New) The method of Claim 36, wherein the assay comprises determination of presence or absence of antibody reaction with at least 10 indicators in the sample.

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60. (New) The method of Claim 57 wherein the at least 3 indicators are selected from the group consisting of *Streptococcus agalactiae*, *Staphylococcus aureus*, *Mycoplasma bovis*, *Streptococcus uberis* and a gram-negative species.

61. (New) The method of Claim 58 wherein the at least 7 indicators are *Streptococcus agalactiae*, *Staphylococcus aureus*, *Mycoplasma bovis*, *Escherichia coli*, coagulase-negative Staphylococci, *Mycoplasma californicum*, *Mycoplasma bovigenitaliae*, and a gram-negative species.

62. (New) The method of Claim 36 wherein the pathogens are selected from the group consisting of: *Staphylococcus aureus*, non-hemolytic *Staphylococci*, *Mycoplasma capricolu*, *Mycoplasma mycoides* subspecies *mycoides*, *Mycoplasma putrefaciens*, *Mycoplasma agalactiae*, *Mycoplasma arginini*, *Mycoplasma conjunctivae*, *Mycoplasma ovipneumoniae*, and *Mycoplasma* strain F38.

63. (New) The method of Claim 36 further comprising a lateral flow test format.

64. (New) The method of Claim 36, further comprising:

immobilizing the antibodies on at least one test membrane.

65. (New) The method of Claim 64, further comprising use of a mobile antibody, wherein the mobile antibody is not bound to the membrane, and wherein the mobile antibody binds to an indicator that is bound to an immobilized antibody.

66. (New) The method of Claim 65, wherein the mobile antibody moves within or along the membrane.

67. (New) The method of Claim 65, wherein the mobile antibody is conjugated to a marker.

68. (New) The method of Claim 67, wherein the marker is a color-producing agent.

69. (New) The method of Claim 68, wherein the color-producing agent is colloidal gold or a micro-sphere.

70. (New) The method of Claim 64, wherein the antibodies are immobilized on two or more separate test membranes.

71. (New) The method of Claim 70, wherein each separate test membrane comprises an antibody specific to one indicator.

72. (New) The method of Claim 70, wherein the two or more test membranes are arranged longitudinally side by side.

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73. (New) The method of Claim 70, wherein the assay comprises concurrent visualization of test results.

74. (New) The method of Claim 36, wherein the antibodies are polyclonal, monoclonal, or parts thereof.

75. (New) The method of Claim 36, wherein the mammal species is a cow, a sheep or a goat.

76. (New) The method of Claim 36, wherein the sample is from an individual animal.

77. (New) The method of Claim 76, wherein the sample is from a distinct quarter of an udder of the animal.

78. (New) The method of Claim 36, wherein the sample is from a plurality of individual animals of the mammal species.

79. (New) A kit for the detection of a plurality of indicators in milk, comprising:
at least two antibodies, wherein each of the at least two antibodies is specific to a corresponding antigen from an indicator, wherein the indicator is selected from the group consisting of: one or more distinct pathogens of a mammal species and a somatic cell of the mammal species; and
a means for visualizing binding of at least one antibody to its corresponding antigen.

80. (New) The kit of Claim 79, further comprising a container which allows the milk to be collected.

81. (New) The kit of Claim 79, further comprising a cleaning product for the removal of organisms from the outside of a milk-producing organ.

82. (New) The kit of Claim 79, wherein the somatic cell is a granulocyte.

83. (New) The kit of Claim 82 wherein the granulocyte is a neutrophil.